BEFORE THE MARYLAND HEALTH CARE COMMISSION

IN THE MATTER OF THE APPLICATION OF SUBURBAN HOSPITAL, INC. FOR A CON TO ESTABLISH A LIVER TRANSPLANT SERVICE	**Docket No. 17-15-2400**

RESPONSE TO CONDITIONAL MOTION TO STAY BY MEDSTAR GEORGETOWN UNIVERSITY HOSPITAL

In accordance with COMAR 10.24.01.10(B), Suburban responds to the conditional motion to stay filed by MedStar Georgetown University Hospital ("MedStar").

Introduction

In two separate matters, MedStar has filed applications to open a liver transplant service and a kidney transplant service at Franklin Square in Rosedale, Maryland. The Johns Hopkins Hospital and the University of Maryland Medical Center filed interested party comments opposing those applications. In addition, the University of Maryland filed a motion for the Commission to stay consideration of both of MedStar's applications in light of impending policy changes concerning the distribution of livers and kidneys.

MedStar opposed the University of Maryland's motion. But it asserted in its opposition that if the Commission were to grant the University of Maryland's motion and stay consideration of MedStar's applications, then the Commission also should stay consideration of Suburban's application. In furtherance of that request, MedStar then filed in this case what it termed "a conditional motion to stay"—the

idea being that if (but only if) the Commission grants the motion by the University of Maryland and stays consideration of MedStar's applications, then the Commission also should halt its consideration of Suburban's application in this matter.

But MedStar was correct to oppose the motion by the University of Maryland. For starters, the University of Maryland was unable to cite any authority for the Commission to order a stay, and it does not appear that the Commission has either the statutory or inherent power to do so. Indeed, if the Commission were to stop its review process every time a change in transplant policy was proposed or implemented, the CON review process would go on indefinitely, with no end in sight. Because organ allocation policies change frequently, the Commission might never complete a review process. That is reason enough to deny MedStar's conditional motion.

Yet even if the Commission had the power to issue a stay, and even if issuing a stay in response to policy changes could be done without prolonging the CON procedure well past its breaking point, the Commission should still deny MedStar's motion. Suburban has identified a need for a second liver transplant service in the Washington metropolitan area *now*. No change in organ allocation is going to fill or eliminate that need. Accordingly Suburban's application should be reviewed and granted and MedStar's conditional motion to stay should be denied.

Background

I. Suburban's Application to Open a Liver Transplant Program.

Suburban filed its application to open a liver transplant program on June 27, 2017. MedStar filed interested party comments. The University of Maryland did not. The basis for Suburban's application is that there is a pressing need for a second liver transplant service in the Washington region. To arrive at this conclusion, Suburban analyzed wide-ranging data from the Organ Procurement and Transplantation Network ("OPTN") and the Scientific Registry of Transplant Recipients ("SRTR") covering the time period of 2010 to 2016. This period covered a policy change implemented in July 2013 called "Share 35." Under Share 35, the sickest patients—those with MELD scores of 35 or higher—are given priority in the allocation of livers.[1] Among other things, Suburban also canvassed peer-reviewed literature concerning the effects of competition among liver transplant programs. Suburban presented its analysis in a 187-page application, supplemented by responses to two rounds of completeness questions.

II. MedStar's Applications to Open Liver and Kidney Transplant Programs.

On August 14, 2017, MedStar filed two separate applications to open liver and kidney transplant services at Franklin Square.[2] MedStar contends that, despite the existence of two high-volume transplant centers in the Baltimore region, a third program is needed so that MedStar patients can remain within the MedStar system.

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[1] MELD stands for Model for End-Stage Liver Disease.

[2] Docket Nos. 17–03–2405 (kidney) and 17–03–2406 (liver).

III. The Motion to Stay by the University of Maryland.

Both The Johns Hopkins Hospital and the University of Maryland filed interested party comments in opposition to MedStar's applications. The University of Maryland also filed a motion to stay review of both applications until policy changes affecting the distribution of livers and kidneys take place. The University of Maryland further requested that at some point in the future, the Commission order MedStar to submit new applications "in light of the new allocation policies." Exhibit 1 (UMMC Motion) at 3. The University of Maryland did not point to any statute or regulation providing the Commission with the authority to issue a stay.

Because donor organs are scarce, procured organs are offered for transplant in a predetermined order of prioritization. When a donor organ is procured by a donor hospital, a list of waiting patients who match with that organ is generated instantaneously in an order of priority determined by the prevailing allocation policy. The OPTN is charged with creating that policy. The OPTN determines how organs are prioritized within three main geographical units: Donation Services Areas ("DSAs"), Regions, and the nation. The DSAs are the primary local units; they are collections of largely contiguous counties. Regions are collections of contiguous DSAs.

Under this model, livers procured "locally" are commonly transplanted "locally," which reduces travel costs and ensures that the organs remain usable. "Sharing" occurs when a procured liver in one DSA is allocated to a transplant center in another DSA. Sharing between DSAs typically occurs between DSAs located within

the same Region. Occasionally, livers are shared between DSAs in different Regions—this is known as national sharing.

The new allocation policy on which the University of Maryland's motion is based is designed to increase sharing among hospitals at greater distances. The policy will allocate livers to the sickest patients within various concentric circles around donor hospitals. The policy will move away from the Donation Service Area-model, relying instead on circles drawn around donor hospitals of distances of 150, 250, and 500 nautical miles—depending on the transplant patient's acuity.[3] While the policy will direct organs to sicker patients within larger geographic areas, the new allocation policy will have no effect on patient mobility, the supply of organs, the local procurement of organs, or the number of transplants that will be performed overall. Nor will the policy affect the service area of transplant programs.

IV. MedStar's Conditional Motion in this Matter.

With respect to its own applications, MedStar opposed the motion to stay by the University of Maryland. Exhibit 2 (MedStar Opp.). MedStar recognized that organ allocation policy is constantly evolving, delays in adoption and implementation of new policies are commonplace, and that it will take years to evaluate the effects of the recent proposals—if and when they are implemented. Because of these factors, MedStar correctly concluded that it would be unreasonable for the Commission to defer review of MedStar's pending applications, await the adoption, implementation, and evaluation of those policies, and then send applicants back to

[3] UNOS has divided the country into 58 separate DSAs. Suburban Application 18. Maryland is split between the Living Legacy Foundation DSA ("LLF DSA") and the Washington Regional Transplant Community DSA ("WRTC DSA").

the drawing board to perform a new analysis. Despite persuasively opposing the University of Maryland's motion, MedStar, "in an abundance of caution," filed in this case a two-page conditional motion. Exhibit 3 (Conditional Motion). MedStar asserts that if the Commission orders a stay of the review of its applications, then the Commission should stay review of all applications—including Suburban's.

In its motion in this case, MedStar made no other arguments as to why a stay should issue. Nor does MedStar contend that the proposed change in liver allocation policy will have any particular application to Suburban's certificate of need.

Argument

I. The Commission Lacks the Inherent Power to Issue a Stay, and If the Commission Agreed to Halt the Review of Applications In Response to Policy Changes, Review Would Go On Indefinitely.

As an initial matter, it does not appear that the Commission has the authority to stay its review of an application for a certificate of need. Nor has the University of Maryland or MedStar pointed to any source for that authority.

A. The Commission Lacks the Power to Order a Stay.

While courts of law have certain inherent powers, including the power to stay proceedings, administrative agencies are limited to the powers granted to them by statute. Before Suburban can open a new transplant service, it must obtain a certificate of need. Maryland Code, § 19–120(e)(1) of the Health General Article. "The Commission's specific mandate by the Legislature is to review and, where appropriate, issue certificates of need. . . ." *Medstar Health* v. *Maryland Health Care Comm'n*, 376 Md. 1, 6, 827 A.2d 83, 86 (2003). But no statute or implementing regulation provides the Commission with the power to stay certificate of need proceedings.

"At least under certain circumstances, the Court of Appeals has recognized the inherent power ***of a court*** to stay proceedings before it." *Waters* v. *Smith*, 27 Md. App. 642, 651–52, 342 A.2d 8, 13 (1975), *aff'd*, 277 Md. 189, 352 A.2d 793 (1976) (emphasis added). While Maryland courts have that inherent power, "such power should be exercised with extreme caution" and, as the appellate courts have recognized, "a stay should not be ordered if it will work injustice." *Id.* (quoting 1 C.J.S., Actions § 132)). By contrast, an administrative agency is a "creature of

statute, [which] has no inherent powers." *Adamson* v. *Corr. Med. Servs., Inc.*, 359 Md. 238, 250, 753 A.2d 501, 507 (2000) (citing *Holy Cross Hosp. Of Silver Spring, Inc.* v. *Health Servs. Cost Review Comm'n,* 283 Md. 677, 683, 393 A.2d 181, 184 (1978)).

Accordingly, unlike a court, the Commission lacks the power to issue a stay, and the failure of the University of Maryland and MedStar to address this threshold issue warrants the denial of both motions without further analysis.

B. Even if this Commission Can Order a Stay, it Should Not Do So.

Even if the Commission has the power to order a stay, a stay should be ordered only with "extreme caution." *Waters*, 27 Md. App. at 651–52, 342 A.2d at 13. A stay here would create a dangerous precedent and would work an injustice. The process by which a health care provider obtains a certificate of need is an arduous and long one. Suburban filed its 187-page Application on June 27, 2017—almost a year and a half ago. In its Application, Suburban analyzed years of data, which spanned policy changes such as Share 35. Suburban has responded to two rounds of completeness questions and interested party comments by MedStar.

In fact, during the pendency of Suburban's application, UNOS proposed a significant change in policy concerning the allocation of livers that never took effect. UNOS proposed that for patients with MELD scores of 29 and above, an additional three points would be added if the patient was listed at a transplant program within a 150-mile radius of the donor hospital. Had the Commission delayed its review in response to that proposed policy change and required Suburban to revise

its analysis in light of that pending change, months and perhaps years would have been wasted.

Furthermore, there is no way to predict the effects of the current proposal to alter the model of distribution. The widening of the distribution area is likely to increase travel times and add significantly to the costs of transplants. The enhanced focus on the sickest patients may have a negative effect on outcomes. Yet the severity of these effects will be measurable only after a significant period of time has elapsed. And there is no way to predict how the public or the OPTN might react to those effects, which may prompt the next—inevitable—policy change.

The question for the Commission is whether Suburban has shown a need now, not whether it can show a need at some indefinite point in the future under circumstances that will not be ascertainable for years to come. As MedStar itself pointed out, organ distribution policy is constantly evolving. If the Commission were to halt its consideration of a CON application every time a policy change was proposed or implemented, the CON review process would never end and quickly become unworkable.

In short, the Commission appears to lack the authority to order a stay, and even if it could order a stay, doing so in response to a proposed change in organ distribution policy would spell the end of the certificate of need process.

II. Suburban Has Identified a Need for a Second Liver Transplant Service in the Washington Metropolitan Area That Will Remain Under Any Organ Allocation Policy.

In its application, Suburban identified a need for a liver transplant program in the WRTC DSA. That DSA covers 5.5 million people, including 2.1 million Maryland residents—but it is served by only a single liver transplant center. The LLF DSA, by contrast, covers 3.9 million people, but has two highly functioning and competitive centers. The single center in the WRTC DSA performs far fewer transplants than the two centers in the LLF DSA. Every year from 2011 through 2017, the centers in the LLF DSA performed more adult liver transplants than the center in the WRTC DSA. In 2015, the LLF DSA centers performed 241 transplants on adult patients. The lone WRTC DSA center (MedStar's program at Georgetown) performed only 49.

Suburban's application is based in part on the need to increase access for patients in the Washington region by establishing a second program to compete with Georgetown. Even if DSAs are eliminated, there remains a need for a second center to compete for patients locally. While the boundaries of the WRTC DSA may cease to exist, the service area will remain. As Suburban has shown, the need for a second center in that service area is acute. The population of the existing WRTC DSA will not change. And that population is underserved by a single center which performs significantly fewer liver transplants than the two centers in the LLF DSA. Moreover, Georgetown lacks the capacity to perform the number of transplants that are currently being performed in the LLF DSA.

The proposed policy change will not eliminate or undermine the benefits of competition. For instance, as Suburban explained in its application, a second center can pick up the slack when the existing center experiences disruptions. In addition, a center in the Washington metropolitan region can better serve patients who are unable or unwilling to travel to Baltimore or elsewhere for evaluation and transplant. Suburban explained that patients in lower socioeconomic status are far less likely to be able to travel to another state in order to be evaluated, placed on a waiting list, to undergo a transplant and to participate in the extensive follow up care required. While a change in policy might make it easier for livers to travel, the policy change at issue will not ease the travel burdens facing a large segment of the population.

In sum, Suburban has identified an existing need for a second liver transplant program in the Washington region. The current proposal to alter the method of distribution of livers will not eliminate the need for a second program. Nor does MedStar contend otherwise.

III. Even if the Commission Defers Review of MedStar's Applications, the Commission Should Move Ahead and Grant Suburban's Application.

Even if the Commission has the power to issue a stay and exercises that power to defer its review of MedStar's applications, it should not halt review of Suburban's application for two reasons.

First, the University of Maryland moved for a stay of MedStar's applications on the ground that MedStar's ability to increase the supply of organs for MedStar patients in the Baltimore region would be rendered irrelevant by the anticipated

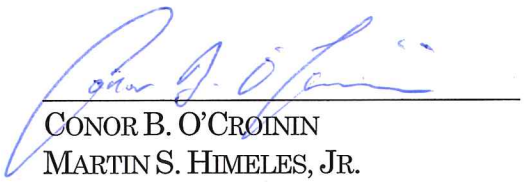
policy changes. In other words, even if MedStar's programs could increase the supply of organs in the Baltimore area—a proposition that both the University of Maryland and The Johns Hopkins Hospital dispute—MedStar's goal of increasing organ availability for MedStar patients will be achievable by increasing the supply of organs at Georgetown. There is no need to establish MedStar programs in Baltimore to achieve this goal. But that rationale does not apply to Suburban. Suburban does not propose to increase the organ supply for only those patients who happen to have been treated within a particular medical system. Rather, Suburban seeks to serve the entire local population in the Washington region and to increase the overall number of transplants for all patients in need. So the grounds for the University of Maryland's motion cannot be transferred here. And in its two-page motion, MedStar does not attempt to argue that they can.

Second, the principal distinction between Suburban's application and MedStar's application is that Suburban has shown a need for a new liver transplant service in the relevant service area, while MedStar has not. Without a second liver transplant program in the Washington region, residents of this service area will remain unable to access liver transplant services at the rates available to residents of the Baltimore area who are served by The Johns Hopkins Hospital and the University of Maryland.

Conclusion

For these reasons, MedStar's conditional cross motion should be denied.

Respectfully submitted,



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CERTIFICATE OF SERVICE

I certify that on November 21, 2018, I caused a copy of Applicant Suburban Hospital's Response to the Conditional Motion to Stay by MedStar Georgetown University Hospital to be emailed and mailed to:

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